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WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/07/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/056,298

Applicant(s)

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1,5 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of applicant's claim for foreign priority to EPO 01400214.1 under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant Application filed on January 25, 2002.

Election/Restrictions

Applicant's election with traverse of the invention of Group II, claims 2 and 6, in Paper No. 8 submitted April 9, 2003 is acknowledged.

The traversal is on the ground(s) that all claims relate to the use of compounds of formula I-IV and they are all classified in the same class and subclass. This is not found persuasive because the invention of Group I functions to treat visceral pain in a patient whereas Group II functions to treat gastrointestinal disorders in a patient. One of ordinary skill in the art would acknowledge that visceral pain may be caused by dysmenorrhea, pelvi inflammation, and cystitis, as Applicant's admits (see the instant specification page 1 lines 21-22). Dysmenorrhea, pelvi inflammation, and cystitis are known to be separate and distinct from gastrointestinal disorders. Each method of treatment relates to a separate and distinct area of pharmaceutical technology as discussed in the Requirement for Restriction mailed March 12, 2003. Therefore, the search for all inventions would place an undue burden on the examiner in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each.

Inventions Group I-II, and III are separate and distinct, related as process of use and product, as discussed in the Requirement for Restriction. Therefore, the inventions

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of Groups I-II, and III are seen to be separate and distinct inventions properly restricted from each other.

Note regarding the classification of the inventions herein that the search is not limited to the patent files. The search field for a composition is non-coextensive with the search field for a method of the treatment employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

As indicated in the in the Requirement for Restriction, claims 3-4 and 7-9 link inventions Groups I and II. Thus, claims 3-4 and 7-9 will be examined with claims 2 and 6 as the elected invention, Group II.

Claims 2-4 and 6-9 will be examined on the merits herein. The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 5 and 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2-4 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of gastrointestinal (GI) disorders disclosed in the specification (for example page 1 lines 25-27) employing the instant compounds herein, does not reasonably provide enablement for the **prevention** of GI disorders by employing the compounds recited in the claims herein.

The instant claims are drawn to the methods for preventing GI disorders. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the method for preventing GI disorders.

The state of the prior art: The skilled artisan would view that the treatment to prevent GI disorders totally, absolutely, or permanently is highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

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The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent GI disorders totally, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to prevent GI disorders totally, absolutely, or permanently.

Therefore, in view of the Wands factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4 and 6-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the method claims 7 and

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8 of copending Application No. 10/124,210 (being allowed) in view of Bryans et al. (WO 99/21824, PTO-1449 submitted June 10, 2002).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method for treating a disease selected from a group of diseases especially including irritable bowel syndrome and inflammatory bowel diseases comprising administering a therapeutically effective amount of the instant compounds.

The claim of the instant application is drawn to methods for the treatment of gastrointestinal disorders such as functional bowel disorders or inflammatory bowel disease comprising administering a therapeutically effective amount of the same compound.

Bryans et al. discloses that gastrointestinal disorders are known to encompass irritable bowel syndrome and inflammatory bowel diseases.

Therefore, one having ordinary skill in the art at the time the invention was made would have been motivated to administer a therapeutically effective amount of the same compound in treating irritable bowel syndrome and inflammatory bowel diseases since the method for treating gastrointestinal disorders are seen to encompass the treatment of irritable bowel syndrome and inflammatory bowel diseases. Thus, these methods of the treatment in between the copending application and the instant application are seen to substantially overlap.

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Thus, the instant claims 2-4 and 6-9 are seen to be obvious over the method claims 7 and 8 of the allowed copending Application No. 10/124,210 in view of Bryans et al. (WO 99/21824).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna. Jiang, Ph.D.
Patent Examiner, AU 1617
April 24, 2003